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REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's communication mailed January 24, 2005. Submitted herewith is a Request for Extension of Time, and required fee, extending the period for responding to the office action to and including May 24, 2005.

Applicant wishes to acknowledge the Examiner for the courtesy shown applicant's attorney during the interview granted on March 17, 2005.

The Abstract has been rewritten in view of the concerns of the Examiner. Applicant submits that the new Abstract is in proper form.

Without conceding the correctness of any of the Examiner's objections/rejections and in order to facilitate the prosecution and allowance of the above-identified application, applicant has canceled claims 1 to 51 and 56 to 65, without prejudice. In addition, claims 52, 53 and 55 have been amended, and new claims 66 to 92 have been added. The present claims read on the elected species set forth in Figs. 7 and 26 of the above-identified application, and are fully supported by the above-identified application as filed.

Applicant expressly reserves the right to obtain patent protection for the original claims and any other claims supported by the present specification in one or more later filed related applications. Specifically, and without limitation, applicant is contemplating filing a divisional application directed to the species of the present invention set forth in Fig. 17.

Since claims 1 to 11 and 13 to 18 have been canceled, without prejudice, and claim 55 has been amended to be dependent upon claim 52, as suggested by the Examiner, applicant submits that the present claims satisfy the requirements of 35 USC 112,

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second paragraph. Therefore, applicant respectfully requests that the rejection of such claims, and in particular claim 55, based on this statutory provision be withdrawn.

With regard to the rejection under 35 USC 101, applicant has amended the existing claims and written new claims to consistently refer to "a human or animal" as opposed to "the human or animal". In view of the above, applicant submits that the present claims are directed to statutory subject matter under 35 USC 101, and respectfully requests that the rejection based on this statutory provision be withdrawn.

Claims 1 to 5, 7 to 11, 13, 14, 16 to 29, 31 to 38, 40 to 51 and 56 to 61 have been rejected under 35 USC 102(b) as being anticipated by Conrad et al. Claims 52 to 55 have been rejected under 35 USC 102(a) and/or 102(e) as being anticipated by Doshi. Claims 6 and 30 have been rejected under 35 USC 103(a) as being unpatentable over Conrad et al. Claim 15 has been rejected under 35 USC 103(a) as being unpatentable over Conrad et al in view of Doshi. Applicant traverses each of these rejections as it pertains to present claims 52 to 55 and 66 to 92.

The present claims are directed to methods and apparatus for treating at least one of sleep apnea or snoring in a human or animal having an oropharyngeal region with lateral and posterior walls.

In independent claim 52, the present methods comprise providing an appliance in or radially outwardly from lateral and posterior walls of an oropharyngeal region of a human or animal so that when so provided is effective in treating at least one of sleep apnea and snoring. In one embodiment (claim 70), the appliance when so provided has at least two substantially laterally positioned elements substantially longitudinally spaced apart from each other. At least one of the elements extends across the posterior wall of the oropharyngeal region.

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In independent claim 82, the present apparatus comprise an appliance comprising two elongated curved elements. Each curved element has a substantially circular dimension between a first end and a second end extending through more than 90°, for example, through at least 180° (see claim 83), of a circle. The two elements are coupled together at respective first and second ends and are spaced apart from each other between the first and second ends. The appliance is sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and, when so placed, the appliance is effective in treating at least one of sleep apnea and snoring.

Conrad et al discloses an implant 20 in the form of a flexible strip for placement in the soft pallet. Conrad et al states that the term "strip" includes long narrow implants, plates and other geometries implanted to alter the dynamic model of the soft pallet. Conrad et al discloses another implant 30 for insertion into the soft pallet through an incision. Conrad et al discloses that the implant 30 has an oval shape to cause deformation of the geometry of the soft pallet. Conrad et al discloses that prior to implantation the implant 30 is formed as a flat oval for ease of insertion. Conrad et al discloses that after implantation the implant 30 is expanded to an enlarged oval shown in Fig. 23.

Conrad et al does not disclose, teach or suggest the present invention. For example, Conrad et al does not disclose, teach or even suggest providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal, as recited in the present method claims. Moreover, Conrad et al does not

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disclose, teach or even suggest an appliance having at least two substantially laterally positioned elements substantial longitudinally spaced apart from each other with at least one of the elements extending across the posterior wall of the oropharyngeal region, as recited in the method present claims 70 to 76. The fact that Conrad et al discloses implants 20 and 30 for placement in the soft pallet clearly, directly and expressly teaches away from providing an appliance in or radially outwardly from lateral and posterior walls of an oropharyngeal region, as recited in the present method claims. Further, applicant notes that the original method claims 52 to 55 were not rejected based on Conrad et al.

In view of the above, applicant submits that claims 52 to 55 and 66 to 81 are not anticipated by and are unobvious from and patentable over Conrad et al under 35 USC 102(b) and 35 USC 103(a).

In addition, Conrad et al does not disclose, teach or suggest the apparatus recited in claims 82 to 92. For example, Conrad et al does not disclose, teach or even suggest an appliance comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90° of a circle with the two elements being coupled together at respective first and second ends and being spaced apart from each other between first and second ends, as recited in independent claim 82.

Implant 20 disclosed by Conrad et al includes only a single strip for placement in a soft pallet and does not disclose, teach or even suggest two spaced apart curved elements, as recited in the present apparatus claims. To a large extent, the disclosure of Conrad et al with regard to implant 20 actually teaches away from the present apparatus.

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With regard to implant 30, Conrad et al does not disclose, teach or even suggest an appliance having two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90° of a circle, as recited in independent claim 82. Conrad et al provides no teaching or suggestion that the implant 30 can be formed to have two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90° of a circle. To the contrary, the ovoid implant 30 disclosed by Conrad et al and shown in Figs. 20 to 23 of Conrad et al is either a flat structure or a curved structure which includes elongated elements that extend between ends through substantially less than 90° of a circle.

Further, applicant submits that the implant 30 of Conrad et al does not inherently disclose the apparatus of the present claims. It is well established that inherency may not be established by probabilities and possibilities. Anticipation by inherency requires that the missing descriptive matter be necessarily present in the prior art reference. Continental Care Co v. Monsanto, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the present situation, the only express disclosure in Conrad et al (Figs. 21 to 23) is that implant 30 forms a curved structure including elongated elements that extend between ends through substantially less than 90° of a circle. It is important to note that Conrad et al discloses only placing implant 30 in the soft pallet. The express disclosure of Conrad et al (Figs. 22 and 23) makes clear beyond doubt that implant 30 is not necessarily formable into a structure comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90° of a circle, as recited in claims 82 to 92. This is

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particularly true since Conrad et al makes clear that the expanded implant 30, shaped as shown in Fig. 23, is effective when implanted in the soft pallet to cause deformation of the geometry of the soft pallet.

In view of the above, applicant submits that claims 82 to 92 are not expressly or inherently anticipated by Conrad et al under 35 USC 102(b) and are unobvious from and patentable over Conrad et al under 35 USC 103(a).

Doshi discloses systems effective to create an obstruction to expiratory air flow within the airways of patients to treat chronic obstructive pulmonary disease. Doshi discloses creating a localized scarring or area of stenosis in the appropriate location, most likely in the trachea, main bronchi or other conducting airways. Doshi further discloses that a device can be implanted in the airways, most likely the trachea or bronchi, that would create a similar obstruction to air flow. In a specific embodiment, Doshi discloses a device having multiple anchoring members, a central rim and a planar element 24 fixed to the central rim and connected to a moveable element 26 by hinge point 23 to form a central valve 21.

Doshi does not disclose, teach or suggest the present invention, for example, as recited in method claims 52 to 55 and 66 to 81. For example, Doshi has absolutely nothing to do with treating sleep apnea or snoring. Further, Doshi does not even suggest placing any device, let alone an appliance as set forth in the present claims, in or radially outwardly from the posterior and lateral walls of an oropharyngeal region, as recited in the present claims. In addition, while the presently claimed methods are advantageously effective to maintain the oropharyngeal region patent and available for airflow both in and out of the lungs, Doshi provides implant devices seeking to

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obstruct the airways to expiratory gases. At least to this extent Doshi actually teaches away from the present invention.

Simply put, the Examiner has no basis for stating that Doshi inherently discloses the methods of the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 52 to 56 and 66 to 81, are not anticipated by and are unobvious and patentable over Doshi under 35 USC 102(a) and 102(e) and 35 USC 103(a).

Moreover, the combination of Conrad et al and Doshi provides no basis for rejecting the present claims. For example, the structures disclosed in each of these references are totally different and distinct one from the other. In addition, whereas Conrad et al discloses placing devices in the soft pallet, Doshi discloses placing implants in airways, such as the trachea and bronchi. The references themselves do not provide any suggestion of the desirability of combining their teachings for any purpose, let alone for the purpose of making obvious the present invention. Put another way, the teachings of Conrad et al and Doshi provide no motivation or incentive to one of ordinary skill in the art to combine their teachings for any purpose, let alone for the purpose of making obvious the present invention.

In view of the above, applicant submits that the present claims, that is claims 52 to 55 and 66 to 92 are not anticipated by and are unobvious from and patentable over Conrad et al and/or Doshi, taken singly or in any combination, under 35 USC 102 and 103.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the present apparatus and methods including the additional feature or features recited in any of the present

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dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. 102 and 103. Therefore, applicant submits that the present claims, that is claims 52 to 55 and 66 to 92, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date.

In the event the Examiner determines that the next communication with the applicant will not be a Notice of Allowance, the Examiner is respectfully requested to telephone applicant's attorney to discuss the matter.

Respectfully submitted,



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